Remarks/Arguments

Reconsideration of the above-identified application in view of the present amendment is respectfully requested.

The specification of the Application has been amended to correct certain informalities. By the present Amendment to the specification, U.S. Patent Nos. 5,197,985 and 5,226,914 and PCT Publication No. WO 92/22584 (1992) are incorporated into the Application by reference in their entirety.

To ensure that the proposed amendment to the specification satisfies the requirements of 35 U.S.C. §112, first and second paragraphs, 37 CFR 1.57(g)(1), and 37 CFR 1.57(g)(2), Applicant respectfully requests that the corrected text at page 3 of the present amendment replace the entire text of the first full paragraph on page 5 of the present application. Applicant respectfully submits that addition of the text from page 3 is proper because: (1) the present application clearly conveys intent to incorporate the material by reference; and (2) the referenced material is sufficiently described in the Application to uniquely identify the documents.

The original application clearly conveys intent to incorporate exemplary techniques and methods of isolating, purifying, and expanding the marrow-derived mesenchymal stems cells in culture, stating on pg. 5:

> "The mesenchymal stem cells can be isolated and prepared according to methods known in the art, for example, a process for isolating, purifying, and expanding the marrow-derived mesenchymal stems cells in culture, *i.e. in vitro*, is described in U.S. Patent Nos. 5,197,985 and 5,226,914 and PCT Publication No. WO 92/22584 (1992), as well as numerous literature references by Caplan and Haynesworth."

Moreover, the referenced material is sufficiently described in the original Application to uniquely identify the documents by means of listing the U.S. Patent Nos. and the PCT Publication No. in the original text.

For example see Southern Clay Products v. United Catalysts, 64 USPQ2d 1606 (Fed. Cir. Unpub. 2002). In Southern Clay Products, clear intent to incorporate by reference and the material was sufficiently described where the Applicants stated in the original application:

> "Exemplary of commonly employed physical or comminuting techniques for breaking the bonds between the colloidal particles in a clay particle aggregate are those techniques disclosed in United States Pat. Nos…."

In addition, similar decisions from the Court of Customs and Patents Appeals (CCPA) are particularly relevant to the present Application, was filed (May 28, 1999) prior to the codification of 37 CFR 1.57 effective October 21, 2004.

In the CCPA decision, In re Hughes, 550 F.2d 1273, 193 USPQ 141 (CCPA 1977), a statement in the specification was found to incorporate another application by reference where:

> "Reference is made to application Ser. No. 131,108 for complete description of methods of preparing aqueous polymeric dispersions applicable in the hereinafter described invention."

See also In re Voss, 557 F.2d 812, 194 USPQ 267 (CCPA 1977), which contained a similar statement which was found by the Court to be an effective incorporation by reference in the specification ("Reference is made to the United States Patent…for a general discussion of glass-ceramic material and their production.")

Accordingly, the amendment incorporating U.S. Patent Nos. 5,197,985 and 5,226,914 and PCT Publication No. WO 92/22584 (1992) by reference in their entirety is proper because the present application clearly conveys intent to incorporate the material by reference; and the referenced material is sufficiently described in the Application to uniquely identify the documents.

In addition claim 6 has been amended to correct informalities.

Below is a discussion of the Specification objections, Claim objection, the 35 U.S.C. §112, first paragraph rejection of claim 6, and the 35 U.S.C. §102(b) rejections of claims 2-6.

1. Specification Objections

The Office Action objected to the specification because it contained a number of informalities. By the present amendment, Applicants have made typographical corrections to the final paragraph on page 12, lines 23-30, continuing onto page 13, lines 1-2. As amended, the present specification, at page 12, now contains primer sequences properly identified with particular SEQ ID NOs in compliance with the requirements of 37 C.F.R. §§1.821-1.825

In addition Applicants have made typographical corrections to the first full paragraph on page 5. As discussed above, U.S. Patent Nos. 5,197,985 and 5,226,914 and PCT Publication No. WO 92/22584 (1992) are incorporated into the Application by reference in their entirety and thus the amended Application now provides a proper antecedent basis for the subject matter of claim 6.

2. Claim Objection

Claim 6 was objected to because of the term "to a" is repeated twice. By the present amendment, Applicants have made a typographical correction to claim 6. Applicants respectfully request that the corrected text of claim 6 of the present amendment replace the deleted text of claim 6.

3. 35 USC §112, first paragraph, rejection of claim 6.

Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Office Action argues that all of the limitations of claim 6 were not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As discussed above, the specification of the present Application has been amended to correct informalities. The specification, as amended, now recites:

> "The mesenchymal stem cells can be isolated and prepared according to methods known in the art, for example, a process for isolating, purifying, and expanding the marrow-derived mesenchymal stems cells in culture, *i.e. in vitro*, is described in U.S. Patent Nos. 5,197,985 and 5,226,914 and PCT Publication No. WO 92/22584 (1992), which are incorporated herein by reference in their entirety, as well as numerous literature references by Caplan and Haynesworth."

As stated in the amendment dated 5/18/09, support for claim 6 can be found in U.S. Patent Nos. 5,197,985 and 5,226,914 and PCT Publication No. WO 92/22584. The specification, as amended, now correctly indicates that U.S. Patent Nos. 5,197,985 and 5,226,914 and PCT Publication No. WO 92/22584 (1992) are incorporated into the present application by reference in their entirety.

Accordingly, the limitation of claim 6 "the human mesenchymal stem cells that have been isolated, purified and culturally expanded from a bone marrow specimen

by adding the bone marrow specimen to a medium which contains factors which stimulate mesenchymal cell growth without differentiation" is adequately described in the present specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the Application was filed, had possession of the invention of claim 6.

4. 35 U.S.C. §102(b) rejection of claims 3-6

Claims 3-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Nolta et al. (Blood 86:101-110, 1995) as evidenced by Prockop, D.J. (Science 276:71-74, 1997) and/or (Mesenchymal stem cell-Wikipedia, the free encyclopedia, page 1-5, 2009).

The office action argues that Nolta et al. discloses a transduction method for human CD34 cells in the presence of a stromal support layer generated by human allogeneic bone marrow stromal cells. The Office Action further states that the bone marrow stromal cell population contains isolated, purified and culturally expanded mesenchymal stem cells expanded from human mesoderm tissue as evidenced by the teachings of Prockop and/or Wikipedia.

Nolta et al. teach the transduction of CD34 cells with retroviral vectors in the presence of an irradiated (20Gy) stromal cell population generated by human allogeneic bone marrow stromal cells. In contrast to language in claim 5, which specifically states the "…co-culturing human hematopoietic progenitor cells with human mesenchymal stem cells isolated, purified and culturally expanded from human mesoderm tissue…", Nolta et al. does not teach the use of human mesenchymal stem cells isolated, purified and culturally expanded from human

mesoderm tissue. In fact, there is no discussion in Nolta et al. of mesenchymal stem cells.

Although the stromal cells used in the method disclosed by Nolta et al. are generated from human allogeneic bone marrow, not used until passage no. 4, devoid of most hematopoietic cells and contain some MSCs per Prockop, these cells are "stromal cells" derived from MSCs and not MSCs which have been isolated, purified and culturally expanded from human mesoderm tissue.

The term "Stromal cells" is defined by the National Institutes of Health resource for stem cell research as "Non-blood cells derived from blood organs, such as bone marrow or fetal liver, which are capable of supporting growth of blood cells *in vitro*. Stromal cells that make the matrix within the bone marrow are also derived from mesenchymal stem cells." (see http://stemcells.nih.gov/StaticResources/info/popups/glossary.html#stromalcells).

In contrast to the irradiated stromal cells of Nolta et al., isolated, purified and culturally expanded Human mesenchymal stem cells (hMSCs) are multipotent and have the capacity to differentiate into more than one tissue type. For example, it is well known in the art that hMSCs can differentiate into bone, cartilage, muscle, and even marrow stroma (see U.S. Pat. No. 5,486,359). Isolated, purified and culturally expanded mesenchymal stem cells are further distinguished from marrow stroma given that they are not only devoid of markers for T and B lymphocytes, macrophages and endothelial cells, but also lack T and B lymphocytes, macrophages and endothelial cell populations themselves (see Application pg. 5, lines 14-17).

Nolta et al., at best teach the culturing of CD34 cells in the presence of an irradiated mesodermic stromal tissue. Nolta et al., do not teach non-irradiated MSCs which have been further isolated, purified and culturally expanded from such a mesodermic tissue. Although bone marrow derived human stroma may include some mesenchymal stem cells, human bone marrow stroma is not equivalent to mesenchymal stem cells which have been isolated, purified and culturally expanded from human mesoderm tissue.

The mesenchymal stem cells of the present application represent a well characterized isolated cell population which can be prepared in a reproducible manner in contrast to the heterogeneous stromal cell cultures described by Prockop. As discussed in Prockop, these heterogeneous stromal cell cultures contain T and B lymphocytes, macrophages, dendritic cells and endothelial cells.

The examiner argues in response to Applicant's previous argument put forth that the stromal cell population is devoid of most hematopoietic cells and contains MSCs as evidenced by Prockop and that this bone marrow derived stromal cell population have many of the characteristics of MSCs.

However, the heterogeneous bone marrow stromal cell population is not mesenchymal stem cells isolated, purified and culturally expanded from human mesoderm tissue even if it shares many characteristics with MSCs. Once isolated, purified and culturally expanded, the mesenchymal stem cells of the present Application can be distinguished from the more complex cellular environment present in adherent cells of long-term bone marrow stromal cultures.

As discussed above, the MSCs of the present application lack surface markers for T and B lymphocytes, macrophages and endothelial cells. The isolated, purified and culturally expanded mesenchymal stem cells for use in the present invention are prepared using detailed procedures described in U.S. Patent Nos. 5,197,985 and 5,226,914 and PCT Publication No. WO 92/22584 (see Application, pg. 5, lines 2-5). The MSCs for example, can be isolated using a density gradient fractionation, such as by Percoll gradient fractionation or selective antibody purification. The resulting morphologically distinct isolated, purified and culturally expanded mesenchymal stem cell population is not equivalent to the bone marrow stromal cells isolated using the crude plastic adherence methods described in Prockop even if the stromal cells are devoid of most hematopoietic cells and contains some MSCs.

The Examiner notes that the instant specification states "These results demonstrate that hMSCs are able to support ex vivo gene transfer into CD34 human hematopoietic progenitor cells that exhibit transduction efficiencies, cell expansion and drug resistance comparable to the levels produced in Dexter Stroma and FN enhanced transduction", and that "Dexter Stroma was derived from adhered bone marrow mononuclear cells that were passaged once". The statements cited by the Examiner were not intended to, nor do they, illustrate that the cell populations of Dexter Stroma and the MSCs isolated from human mesoderm tissue are substantially identical cell populations. This statement was merely included in the present Application to illustrate the effectiveness of the present invention in relation

to other methods of ex vivo gene transfer into CD34 human hematopoietic progenitor cells known at the time of the present invention.

The Office Action further argues that the stromal cells of Nolta et al. are in fact MSCs because, in part, the terms "Mesenchymal stem cell" and "Marrow stromal cells" have been used interchangeably in the art as evidenced by Wikipedia. However, Nolta et al. does not include the term "marrow stromal cells" within the reference. Nolta et al. simply refer to "stromal cells" which are generated from bone marrow prior to the transduction of CD34 cells but not "marrow stromal cells" in reference to a multipotent stem cell of any kind capable of differentiating into more than one tissue type.

Furthermore, the Applicant respectfully submits that Wikipedia is an invalid evidentiary reference and cannot properly be utilized in rejection of patent application claims. As described by the source itself (see, http://en.wikipedia.org/wiki/Wikipedia:About) *articles can be edited by anyone with access to the internet* and *articles frequently contain significant misinformation*.

The most recent Office Action argues that stromal cells of Nolta et al. are identical to, or substantially identical to the MSCs of the present invention. As discussed above, the Office Action has failed to provide evidence that the stromal cells of Nolta et al. in view of Prockop and/or Wikipedia are identical to, or substantially identical to the MSCs (or necessarily or inherently possess all of the properties of MSCs) of present claim 5.

To overcome this deficiency in the rejection, the Examiner argues in the most recent Office Action that "stromal cells used in the method of Nolta et al. for the

transduction of human CD34 cells with retroviral vectors are, in fact, mesenchymal stem cells that have been isolated, purified and culturally expanded from human mesoderm tissue". Essentially, the Office Action is arguing that, the use of MSCs in a method of transducing CD34 cells is inherent in view of the Nolta et al. disclosure of the transduction of CD34 cells with retroviral vectors in the presence of a stroma generated by human allogeneic bone marrow stromal cells which are irradiated prior to use. As discussed above, there is nothing in Nolta et al., Prockop and/or Wikipedia that suggests that these irradiated stromal cells are equivalent to MSCs which have been isolated, purified and culturally expanded from human mesoderm tissue nor has the Examiner provided any evidence in fact or technical literature to support this assertion.

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ 2d. 1955, 1957 (Fed. Cir. 1993). To establish inherency, the extrinsic evidence "must make clear the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a give set of circumstances is not sufficient." *In re Robertson*, 169 F.3d 743,745, 49 USPQ2d 1949, 1950-1951.

The Examiner must provide a basis in fact or technical reasoning to reasonably support the determination that the allegedly inherent characteristics necessarily flow from the teachings of the applied reference. *Ex Parte Levy*, 17

USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). The Examiner has, however, provided no evidence in fact or technical reasoning that the use of MSCs which have been isolated, purified and culturally expanded from human mesoderm tissue in a method of transforming hematopoietic progenitor cells to express a protein is inherent in view of the Nolta et al. disclosure of transduction of CD34 cells with retroviral vectors in the presence of a stroma generated by human allogeneic bone marrow stromal cells which are irradiated prior to use. Absence such a showing that this characteristic necessarily flows from the stromal cells of Nolta et al, Nolta et al. cannot be relied on to teach the use of MSCs which have been isolated, purified and culturally expanded from human mesoderm tissue in a method of transducing CD34 cells. Accordingly, the burden of establishing that the stromal cells of Nolta et al. necessarily or inherently possess the characteristics of the present claimed invention remains with the Examiner.

In view of the present Amendment, the Applicant respectfully requests that the 35 U.S.C. §102(b) rejection of claim 5 be withdrawn because Nolta et al. as evidenced by Prockop do not teach all the limitations of claim 5. Claims 3 and 4 depend either directly or indirectly from claim 5, and therefore should be allowed because of the aforementioned deficiencies in the rejection with respect to claim 5 and because of the specific limitation recited in claims 3 and 4.

Claim 6 includes all the elements of claim 5 and the further limitation of human mesenchymal stem cells that have been isolated, purified and culturally expanded from a bone marrow specimen by adding the bone marrow specimen to a medium which contains factors which stimulate mesenchymal cell growth without

differentiation. Claim 6 should be allowed for at least the same reasons as claim 5 and because of the specific limitation recited in claim 6.

5. 35 U.S.C. §102(b) rejection of claims 2 and 4-6

Claims 2 and 4-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Wells et al. (Gene therapy 2:512-520, 1995) as evidenced by Prockop, D.J. (Science 276:71-74) and/or (Mesenchymal stem cell-Wikipedia, the free encyclopedia, page 1-5, 2009).

The office action argues that Wells et al. discloses a transduction method for human bone marrow CD34 progenitor cells in the presence of an autologous bone marrow stromal support containing isolated mesenchymal stem cells as evidenced by the teachings of Prockop as described above.

Claim 5 of the present invention is not anticipated by Wells et al. because like Nolta et al., Wells et al. does not teach the co-culturing human hematopoietic progenitor cells with human mesenchymal stem cells isolated, purified and culturally expanded from human mesoderm tissue…" At best Wells et al. teach the culturing of CD34 cells in the presence of an irradiated mesodermic tissue. Wells et al. do not teach the use of MSCs isolated, purified and culturally expanded from such a mesodermic tissue.

As discussed above, the mesenchymal stem cells of the present application represent a well characterized isolated, purified and culturally expanded cell population which can be prepared in a reproducible manner in contrast to the

heterogeneous stromal cell cultures described by Prockop. As discussed in Prockop, these heterogeneous stromal cell cultures contain T and B lymphocytes, macrophages, dendritic cells and endothelial cells. Isolated mesenchymal stem cells of the present invention are distinguished from the complex microenvironment present in marrow stroma given that MSCs are distinct in morphology and lack surface markers for T and B lymphocytes, macrophages and endothelial cells (see Application pg. 5, lines 14-17).

The isolated, purified and culturally expanded mesenchymal stem cells for use in the present invention are isolated and prepared using procedures described in U.S. Patent Nos. 5,197,985 and 5,226,914 and PCT Publication No. WO 92/22584 (see Application, pg. 5, lines 2-5). The MSCs for example, can be isolated using a density gradient fractionation, such as by Percoll gradient fractionation or selective antibody purification. The resulting morphologically distinct isolated, purified and culturally expanded mesenchymal stem cell population is not equivalent to the bone marrow stromal cells isolated using the crude plastic adherence methods described in Prockop.

Furthermore, the Prockop reference states that although the adherent cells used as feeder layers for hematopoietic stem cells have many of the characteristics of mesenchymal stem cells, which are isolated by their adherence to plastic in the absence of non-adherent cells, it is not clear if the adherent cells contain true mesenchymal stem cells. Prockop states that it is uncertain that the adherent feeder cells retain the potential to differentiate into bone, cartilage, and other mesenchymal cells. Prockop even suggests that the adherent cells may have differentiated into

another and discrete phenotype because of their continuing interaction with hematopoietic cells (pg. 72, col. 3).

The examiner argues in response to Applicant's previous argument put forth that the stromal cell population is devoid of most hematopoietic cells and contains MSCs as evidenced by Prockop and that this bone marrow derived stromal cell population have many of the characteristics of MSCs.

However, the heterogeneous bone marrow stromal cell population is not mesenchymal stem cells isolated, purified and culturally expanded from human mesoderm tissue even if it shares many characteristics with MSCs. Once isolated, purified and culturally expanded, the mesenchymal stem cells of the present Application can be distinguished from the more complex cellular environment present in adherent cells of long-term bone marrow stromal cultures.

As discussed above, the MSCs of the present application lack surface markers for T and B lymphocytes, macrophages and endothelial cells. The isolated, purified and culturally expanded mesenchymal stem cells for use in the present invention are prepared using detailed procedures described in U.S. Patent Nos. 5,197,985 and 5,226,914 and PCT Publication No. WO 92/22584 (see Application, pg. 5, lines 2-5). The MSCs for example, can be isolated using a density gradient fractionation, such as by Percoll gradient fractionation or selective antibody purification. The resulting morphologically distinct isolated, purified and culturally expanded mesenchymal stem cell population is not equivalent to the bone marrow stromal cells isolated using the crude plastic adherence methods described in

Prockop even if the stromal cells are devoid of most hematopoietic cells and contains some MSCs.

The Examiner notes that the instant specification states "These results demonstrate that hMSCs are able to support ex vivo gene transfer into CD34 human hematopoietic progenitor cells that exhibit transduction efficiencies, cell expansion and drug resistance comparable to the levels produced in Dexter Stroma and FN enhanced transduction", and that "Dexter Stroma was derived from adhered bone marrow mononuclear cells that were passaged once". The statements cited by the Examiner were not intended to, nor do they, illustrate that the cell populations of Dexter Stroma and the MSCs isolated from human mesoderm tissue are substantially identical cell populations. This statement was merely included in the present Application to illustrate the effectiveness of the present invention in relation to other methods of ex vivo gene transfer into CD34 human hematopoietic progenitor cells known at the time of the present invention.

The Office Action further argues that the stromal cells of Wells et al. are in fact MSCs because the terms "Mesenchymal stem cell" and "Marrow stromal cells" have been used interchangeably in the art as evidenced by Wikipedia. However, Wells et al. does not include the term "marrow stromal cells" within the reference. Wells et al. simply refer to "stromal cells" which are generated from bone marrow prior to the transduction of CD34 cells but not "marrow stromal cells" in reference to a multipotent stem cell of any kind capable of differentiating into more than one tissue type.

Furthermore, the Applicant respectfully submits that Wikipedia is an invalid evidentiary reference and cannot properly be utilized in rejection of patent application claims. As described by the source itself (see, http://en.wikipedia.org/wiki/Wikipedia:About) *articles can be edited by anyone with access to the internet* and *articles frequently contain significant misinformation*.

The most recent Office Action argues that stromal cells of Wells et al. are identical to, or substantially identical to the MSCs of the present invention. As discussed above, the Office Action has failed to provide evidence that the stromal cells of Wells et al. in view of Prockop and/or Wikipedia are identical to, or substantially identical to the MSCs (or necessarily or inherently possess all of the properties of MSCs) of present claim 5.

To overcome this deficiency in the rejection, the Examiner argues in the most recent Office Action that stromal cells used in the method of Wells et al. for the transduction of human CD34 cells with retroviral vectors are, in fact, mesenchymal stem cells that have been isolated, purified and culturally expanded from human mesoderm tissue. Essentially, the Office Action is arguing that, the use of MSCs in a method of transducing CD34 cells is inherent in view of the Wells et al. disclosure of the transduction of CD34 cells with retroviral vectors in the presence of a stroma generated by human autologous bone marrow stromal cells which are irradiated prior to use. As discussed above, there is nothing in Wells et al., Prockop and/or Wikipedia that suggests that these irradiated stromal cells are equivalent to MSCs which have been isolated, purified and culturally expanded from human mesoderm

tissue nor has the Examiner provided any evidence in fact or technical literature to support this assertion.

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ 2d. 1955, 1957 (Fed. Cir. 1993). To establish inherency, the extrinsic evidence "must make clear the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a give set of circumstances is not sufficient." *In re Robertson*, 169 F.3d 743,745, 49 USPQ2d 1949, 1950-1951.

The Examiner must provide a basis in fact or technical reasoning to reasonably support the determination that the allegedly inherent characteristics necessarily flow from the teachings of the applied reference. *Ex Parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). The Examiner has, however, provided no evidence in fact or technical reasoning that the use of MSCs which have been isolated, purified and culturally expanded from human mesoderm tissue in a method of transforming hematopoietic progenitor cells to express a protein is inherent in view of the Wells et al. disclosure of transduction of CD34 cells with retroviral vectors in the presence of a stroma generated by human autologous bone marrow stromal cells which are irradiated prior to use. Absence such a showing that this characteristic necessarily flows from the stromal cells of Wells et al, Wells et al. cannot be relied on to teach the use of MSCs which have been isolated, purified and

culturally expanded from human mesoderm tissue in a method of transducing CD34 cells. Therefore, the burden of establishing that the stromal cells of Wells et al. necessarily or inherently possess the characteristics of the present claimed invention remains with the Examiner.

Accordingly, Applicants respectfully request that the 35 U.S.C. §102(b) rejection of claim 5 be withdrawn because Wells et al. as evidenced by Prockop do not teach all the limitations of claim 5. Claims 2 and 4 depend either directly from claim 5, and therefore should be allowed because of the aforementioned deficiencies in the rejection with respect to claim 5 and because of the specific limitation recited in claims 2 and 4.

Claim 6 includes all the elements of claim 5 and the further limitation of human mesenchymal stem cells that have been isolated, purified and culturally expanded from a bone marrow specimen by adding the bone marrow specimen to a medium which contains factors which stimulate mesenchymal cell growth without differentiation. Claim 6 should be allowed for at least the same reasons as claim 5 and because of the specific limitation recited in claim 6.

In view of the foregoing, it is respectfully submitted that the present application is in a condition of allowance and allowance of the present application is respectfully requested.

Please charge any deficiency or credit any overpayment in the fees for this matter to our Deposit Account No. 20-0090.

Respectfully submitted,

/Richard A. Sutkus/
Richard A. Sutkus
Reg. No. 43,941

TAROLLI, SUNDHEIM, COVELL,
& TUMMINO L.L.P.
1300 East Ninth Street, Suite 1700
Cleveland, Ohio 44114
Phone:(216) 621-2234
Fax: (216) 621-4072
Customer No.: 68,705